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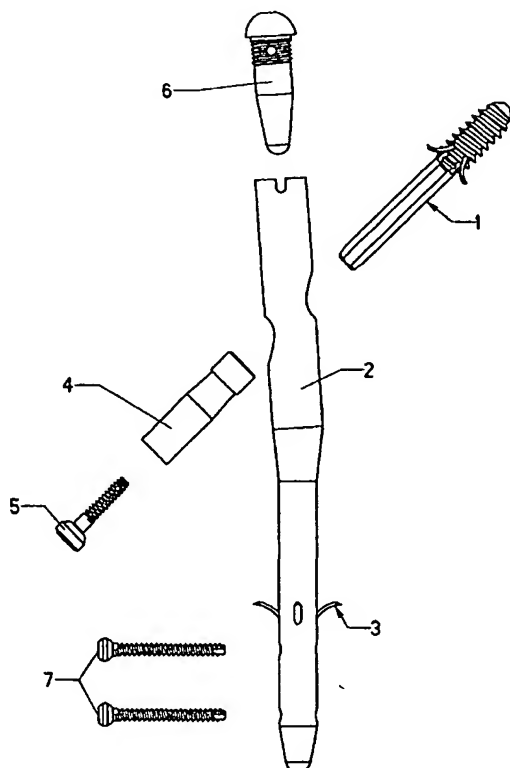
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[Continued on next page]

(54) Title: FERMORAL NAIL INTRAMEDULLARY SYSTEM



(57) Abstract: An intramedullary system for securing portions of a bone together has a lag screw assembly extending through a radial bore in an intramedullary nail. The lag screw is inserted into one portion of a bone and deployed to fix the leading end. The intramedullary nail is placed in the intramedullary canal of a portion of the bone and the trailing end of the lag screw assembly is adjustably fixed in the radial bore to provide compression between the lag screw assembly and the intramedullary nail. The intramedullary nail has a cap screw in the proximal end holding the lag screw assembly and a tang in the distal end. The tang has legs extending through the nail to fix the distal end in the intramedullary canal.

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## FERMORAL NAIL INTRAMEDULLARY SYSTEM

FIELD OF THE INVENTION

The present invention generally relates to an intramedullary system for coupling bone portions across a fracture therebetween and, more specifically, to an intramedullary hip pinning system for rigidly interconnecting a femoral head portion to the remaining portion(s) of the femur and across a fracture or fractures in the area of the femoral neck or the shaft of the femur or combinations of such fractures.

BACKGROUND OF THE INVENTION

Bones are the hard parts of the skeleton found in vertebrates. In its most basic construct, bones are formed of a relatively soft, spongy cancellous material surrounded by a much harder cortex. The cancellous bone yields under relatively low loading, while the much more dense cortical bone supports much higher loading.

A hip joint is a heavily stressed, load-carrying bone joint in the human body. It is essentially a ball and socket joint formed by the top of the femur which rotates within a cup-shaped acetabulum at the base of the pelvis. When a break or fracture occurs adjacent to the top of the femur, the separated portions of the femur must be held together while healing occurs.

Historically, there have been a number of techniques used for treatment of fractures of the proximal end of the femur. In early parts of this century, patients were merely placed in bed or in traction for prolonged periods, frequently resulting in deformity or death.

In the 1930s, the Smith-Peterson nail was introduced. This device was inserted into the intramedullary canal of the femur resulting in immediate fixation of hip fractures, early mobilization of the patient, and a lower morbidity and

1 mortality. A number of nails have been introduced for fracture  
2 fixation of the femur in its proximal end, including the Jewett  
3 Nail and Enders Nail.

4 Intramedullary nails have been inserted down the entire  
5 length of the femoral canal to provide a basis for the fixation.  
6 Threaded wires, standard bone screws or cannulated bone screws  
7 were then inserted through or along side the proximal nail and  
8 into the femoral head to provide fixation and rotational  
9 stability. The conventional nails did not provide compression  
10 of the proximal bone fragments against each other. Also, in  
11 longer nails the distal tip of the nail tended to rotate out of  
12 plane which forced the surgeon to locate the distal screw holes  
13 using fluoroscopy by a method commonly known as "free-handing".

14 In the 1960s, the compression hip screw was introduced,  
15 resulting in improved fixation of the proximal femur. A lag  
16 screw assembly was inserted into the femoral head, a plate was  
17 attached to the lateral femur, and a compression screw joined  
18 the two. These implants provided a more rigid structure for the  
19 patient and allowed the surgeon to compress the fractured  
20 fragments against each other thereby decreasing the time to  
21 mobility. A number of compression hip screws have been  
22 introduced for fracture fixation about the proximal femur,  
23 including the Dynamic Hip Screw.

24 During implantation these compression hip screws require  
25 an incision at least equal to the length of the plate being used  
26 which extends operative time and blood loss. The side plate  
27 also creates a protuberance on the lateral side which provides  
28 an annoyance to the patient. Compression hip screw systems also  
29 fail to provide adequate compression in osteoporotic patients  
30 because the lag screw assembly threads fail to obtain sufficient  
31 purchase due to poor bone stock. Poor purchase is known to  
32 contribute to nonunion, malunion and the lag screw assembly  
33 eroding through the superior bone of the head of the femur in

1 a condition known as "cut out". Additionally, many patients are  
2 dissatisfied with the results of compression hip screw surgery  
3 because of the excessive sliding to a medial displacement and  
4 shortening position which leads to a change in gait.

5 Newer devices and inventions include additions to the  
6 nail and lag screw assembly to ease or eliminate the need to  
7 locate the distal screw holes and improve the fixation. These  
8 newer devices are commonly classified as "expanding devices" and  
9 expand in size after placement to fill the intramedullary  
10 cavity. Freedland, U.S. Patent No.s 4,632,101, 4,862,883 and  
11 4,721,103, Chemello, U.S. Patent No. 6,077,264 and Davis, U.S.  
12 Patent No. 5,057,103 describe a method of fixation which  
13 provides points which contact the internal cortical wall. In  
14 these patents a mechanism is actuated deploying arms or anchor  
15 blades through the cancellous bone to contact the inner cortical  
16 wall. These methods are complex and difficult to retract should  
17 the nail or lag screw assembly require extraction. Further, the  
18 screws do not deploy through the cortical bone.

19 Other expanding devices provide surface contact with the  
20 internal cortical wall resulting in a wedge effect. Kurth, U.S.  
21 Patent No. 4,590,930, Raftopoulos, U.S. Patent No. 4,453,539 and  
22 Aginski, U.S. Patent No. 4,236,512, among others have described  
23 mechanisms which deploy or expand with a molly bolt concept.  
24 These methods are complex and difficult to retract should the  
25 nail or lag screw assembly require extraction and, also, do not  
26 deploy through the cortical bone.

27 Bolesky, U.S. Patent No. 4,275,717 was the first to  
28 discuss engagement within the cortical wall. However, Bolesky's  
29 invention does not address controlled penetration into the wall  
30 and required permanent implantation of the actuation rod. In  
31 addition, Bolesky does not address the fundamental problem of  
32 the actuation rod's protrusion extramedullarly into the  
33 surrounding musculature.

1        In U.S. Patent No.s 5,976,139 and 6,183,474B1, Bramlet et  
2        al describe a surgical anchor which has deployable tangs. These  
3        tangs are simple in design, internally positioned, yet easily  
4        deployed into, and if desired through, the cortical bone  
5        providing improved purchase for compression of a fracture,  
6        especially in osteogenic bone. These tangs are just as easily  
7        retracted should the device require explantation.

8        Approximately 10 years ago Howmedica (Rutherford, New  
9        Jersey, United States) was the first to produce the "Gamma  
10       Nail", named for its similarity in shape to the Greek letter,  
11       and other designs soon followed. These devices combined  
12       desirable aspects of both intramedullary nails and compression  
13       hip screws. These intramedullary hip compression screws  
14       required a few small incisions, allowed capture of the most  
15       proximal fragments of the femur, rigid fixation of the most  
16       proximal and distal fragments, and a sliding lag screw assembly  
17       or anchor which fits within a barreled sleeve for allowing  
18       improved compression of the fragments as the patient ambulates  
19       and begins to bear weight on the fractured limb. The nails are  
20       typically held in place on the distal end through interference  
21       forces with the intramedullary canal and through the use of  
22       locking screws.

23       The Gamma Nail's shape accommodates the relative shape of  
24       the greater trochanter and femoral neck and head fragments, and  
25       the shape of the hip is therefore preserved. Nonunions are less  
26       frequent because bone-to-bone contact is maintained and the bulk  
27       of an intramedullary hip screw blocks excessive sliding.  
28       Intramedullary hip screws work best in reverse obliquity  
29       fractures, a fracture, in which compression hip screws are least  
30       effective.

31       Osteogenic bone still provides a poor medium for purchase  
32       of the lag screw assembly of the Gamma Nail inhibiting adequate  
33       compression and rotational stability. Longer nails continue to

1 see the distal tip of the nail rotating out of plane forcing the  
2 surgeon to locate the distal screw holes by the free-hand  
3 method. The free-handing technique leads to an increased  
4 surgical time and exposes the surgeon and patient to increased  
5 radiation dosages.

6 Clearly a need exists for a system which is superior to  
7 the, " gold standard," of compression hip screws while  
8 minimizing the surgical insult to the human body. Such a  
9 system, as disclosed and claimed herein, includes a simple,  
10 effective and controllable fixation device which allows greater  
11 purchase of the lag screw assembly within the femoral head,  
12 improved compression across the fracture line, provides a means  
13 of rotational stability both in the femoral head and in the  
14 femoral shaft, and minimizes the need for additional distal  
15 incisions to locate and place locking screws. This system  
16 allows the surgeon a choice of penetration distance within the  
17 femoral head and femoral shaft fixation based upon the injuries  
18 presented and the desired level of treatment. Finally, this  
19 system allows explantation to occur as easily as implantation.

#### 20 21 SUMMARY OF THE INVENTION

22 An intramedullary nail system is provided for coupling  
23 bone portions on opposite sides of a fracture. The  
24 intramedullary nail system according to the invention is  
25 especially suitable for installation within the medullary canal  
26 of a fractured long bone, such as found in an arm or leg. In  
27 one embodiment of the present invention, the intramedullary nail  
28 system includes an elongated rod with radial portals which allow  
29 passage of locking screws or anchoring tangs and a lag screw  
30 assembly. The rod has a distal end and a proximal end with  
31 internal threads. A lag screw assembly having an externally  
32 threaded portions. The radial portals in the distal end allow  
33 passage of internally deployable and retractable anchoring

1     tangs or cortical screws. A radial portal in the proximal end  
2     accommodates a sleeve which passes through the intramedullary  
3     nail and through which the lag screw assembly passes freely  
4     while preventing rotation of said lag screw assembly. A  
5     compression screw engages the sleeve and cooperates with the  
6     internal threads of the lag screw assembly trailing end  
7     providing axial translation of the lag screw assembly within the  
8     sleeve. The proximal end has an axial portal for an end cap  
9     with external threads on the trailing end which engages the  
10    internal threads of the intramedullary nail. The end cap has  
11    a parabaloid leading end which engages the sleeve thereby  
12    preventing translation and rotation of said sleeve.

13         When the intramedullary nail is placed into position the  
14    anchoring tang assembly is actuated to deploy the tangs out from  
15    their stowed position into the cortical bone. The tangs are  
16    deployed to any desired position thereby achieving a desired  
17    fixation based upon the quality of the bone.

18         In one embodiment, cortical screws may be placed to  
19    secure the intramedullary nail with the surrounding cortical  
20    bone. In another embodiment, the tang assembly is actuated and  
21    the tangs are deployed to any desired position thereby achieving  
22    the desired fixation based upon the quality of the bone.

23         The sleeve is coaxially inserted over the lag screw  
24    assembly's trailing end and through the intramedullary nail.  
25    An end cap is threaded into the intramedullary nail with it's  
26    leading end contacting and frictionally holding the sleeve. By  
27    providing interference against the sleeve, the sleeve is  
28    prevented from altering its position either through translation  
29    or rotation.

30         The compression screw passes through the sleeve and  
31    engages the lag screw assembly. As the compression screw is  
32    tightened the lag screw assembly and associated first bone  
33    portion are pulled against the intramedullary nail and second



1 bone portion resulting in compressive forces being applied  
2 across the fracture.

3 The intramedullary nail is preferably cannulated to allow  
4 passage of one or more anchoring tang assemblies. These  
5 anchoring tang assemblies are inserted from the proximal end  
6 towards the distal end and the tangs deployed by means of an  
7 actuator driver. An alternate embodiment describes a retracted  
8 anchoring tang assembly which is permanently placed within the  
9 distal end of the intramedullary nail and is deployed or  
10 retracted by means of an actuator driver from the proximal end  
11 of the intramedullary nail.

12 The lag screw assembly preferably contains a permanently  
13 placed anchoring tang assembly stored in a retracted position  
14 within the leading end. The tangs are deployed or retracted  
15 from the trailing end of the lag screw assembly.

16 The anchoring tang assembly contains arcuate shaped tangs  
17 that are permanently attached to the assembly's main body.  
18 These tangs are initially formed into a prescribed position for  
19 storage. As the assembly is actuated, and the tangs deploy, the  
20 tangs are formed into their final shape through interaction with  
21 the portal of either the intramedullary nail or the lag screw  
22 assembly.

23 The compression screw preferably contains a patch of  
24 ultra-high molecular weight poly-ethylene (UHMWPE) within the  
25 threads. This provides constant positive engagement between the  
26 compression screw external threads and the lag screw assembly  
27 internal threads.

28 The end cap preferably contains a patch of ultra-high  
29 molecular weight poly-ethylene (UHMWPE) within the threads.  
30 This provides constant positive engagement between the end cap  
31 external threads and the intramedullary nail internal threads.

32

1 In its final position the end cap exerts a force upon the sleeve  
2 which inhibits the sleeve from sliding or rotating out of a  
3 prescribed position.

4 Other objectives and advantages of this invention will  
5 become apparent from the following description taken in  
6 conjunction with the accompanying drawings wherein are set  
7 forth, by way of illustration and example, certain embodiments  
8 of this invention. The drawings constitute a part of this  
9 specification and include exemplary embodiments of the present  
10 invention and illustrate various objects and features thereof.

11

12 DESCRIPTION OF THE DRAWINGS

13 FIG. 1, is a longitudinal perspective view of the preferred  
14 embodiment intramedullary system in an exploded state;

15 FIG. 2, is a view, partially in longitudinal cross section, of  
16 the intramedullary system placed in the intramedullary canal of  
17 a fractured bone using cortical screws as a method of fixation;

18 FIG. 3, is a view, partially in longitudinal cross section, of  
19 the intramedullary system placed in the intramedullary canal of  
20 a fractured bone using a tang assembly as a method of fixation;

21 FIG. 3A, is an enlarged, cross section view of the tang assembly  
22 in FIG. 3;

23 FIG. 3B, shows the stowed tang assembly from FIG. 3A;

24 FIG. 3C shows the insertion/deployment/retraction instrument  
25 of FIG. 3A;

26 FIG. 4A, is an enlarged, cross section view of the  
27 intramedullary nail in FIG. 1;

28 FIG. 4B, is a side view of FIG. 4A;

29 FIG. 4C, is an end view of FIG. 4B;

30 FIG. 5, is an enlargement of the lag screw assembly in FIG. 1;

31 FIG. 6A, is an enlargement of the tang assembly in FIG. 3A;

32 FIG. 6B, is an enlargement of the stowed tang assembly from FIG.  
33 3B;

- 1 FIG. 6C, is a top view of FIG. 6B;  
2 FIG. 7A, is an enlargement of the sleeve in FIG. 1;  
3 FIG. 7B, is a cross section view of FIG. 7A;  
4 FIG. 7C, is an end view of FIG. 7A;  
5 FIG. 8A, is an enlargement of the end cap in FIG. 1;  
6 FIG. 8B, is a top view of FIG. 8A;  
7 FIG. 9A, is an enlargement of the compression screw in FIG. 1;  
8 FIG. 9B, is a top view of FIG. 9A;

9

10 DETAILED DESCRIPTION

11 The individual components of the assembly, as illustrated  
12 in FIG.1, are constructed of implantable grade stainless steel  
13 alloys in the preferred embodiment but could also be constructed  
14 of implantable grade titanium alloys, as well. Other materials  
15 having the requisite properties, of strength and inertness, may  
16 be used. These components consist of the lag screw assembly  
17 1, the nail body 2, the tang assembly 3, the sleeve 4, the  
18 compression screw 5, and the end cap 6 and the optional cortical  
19 screws 7.

20 The lag screw assembly 1 is described in detail in U.S.  
21 Patent 6,183,474 B1, as is compression screw 5, and that  
22 disclosure is incorporated herein by reference. The external  
23 features of the lag screw assembly are indicated in FIG.5. The  
24 threads 8 engage the cancellous bone within the femoral head on  
25 the medial or proximal side of the fracture line; the tang 9 is  
26 also located on the medial or proximal side of the fracture  
27 line as shown in FIG. 3. However, the tangs 9 are fully  
28 retracted into the body of the lag screw and remains that way  
29 until the lag screw assembly is fully positioned within the  
30 femoral head. When the tangs 9 are deployed through opening 43  
31 into the femoral head, the tangs 9 penetrate the cortical bone,  
32 greatly increasing purchase (axial fixation) and rotational  
33 stability of the lag screw assembly. The tangs 9 are fully

1 reversible if removal of the lag screw is ever required. As  
2 shown, the bone screw threads and the tangs are preferred,  
3 however either one of the structures may be used, alone, to  
4 attach the lag screw assembly to the bone. The shaft 10 is of  
5 a "double D " cross section which interfaces with bore 27 (FIG.  
6 7B) and end configuration 31 (FIG. 7C) of the sleeve in such a  
7 way as to allow axial translation or slide of the lag screw  
8 while preventing rotation relative to the sleeve. This sliding  
9 prevents penetration of the femoral head by the proximal end of  
10 the lag screw as the fracture compresses from patient load  
11 bearing.

12 The nail body (FIG. 4A,B, C) is designed for antegrade  
13 insertion into the intramedullary canal of the femur. It is  
14 anatomically shaped to the axis of the canal and has a medial  
15 to lateral bend angle H. The proximal outside diameter W of the  
16 body is greater than the distal outside diameter M due to  
17 narrowing of the canal and to allow the lag screw clearance  
18 radial bore 11 to be large enough to pass the threaded diameter  
19 8 of the lag screw 1 and provide a sliding fit to the outside  
20 diameter L of the sleeve 4. The axis of clearance bore 11 is  
21 at an angle V with respect to the distal diametral axis. This  
22 angle V is such as to allow proper positioning of lag screw 1  
23 within the femoral head. Both the proximal axial bore 15 and  
24 the distal axial bore 14 are of circular cross section. Distal  
25 bore 14 is sized to permit a sliding fit with the tang body 20.  
26 Four bores or tang portals 12 are located on a 90 degree radial  
27 spacing penetrating from the distal outside diameter M into the  
28 distal bore 14, on axes which form an angle J to the distal  
29 outside diameter M. This angle J is critical to the proper  
30 formation and exit of the tang 21. The clearance holes or bores  
31 13 of FIG.4B pass through the distal outside surface and wall  
32 into the distal bore 14 and continue on the same axis through  
33 the opposite wall and outer diameter. The clearance holes 13 are

1 such as to allow passage of the threaded portion of the cortical  
2 screw 7 (FIG.1). A frusto-conical feature 18 (FIG.4A) provides  
3 a transition between the circular bore 14 and the square bore  
4 19. The square bore 19 serves three purposes: it provides  
5 clearance through the distal end of the nail body 2 for passage  
6 of a guide pin, used during fracture alignment and installation  
7 of the of the nail body into the intramedullary canal, it  
8 provides a sliding fit for the square forward protrusion 23  
9 (FIG.6A) of tang assembly 3, and it acts as a "vent" hole for  
10 any organic material within the bore 14 which is being pushed  
11 ahead of the tang during tang installation. It must be noted  
12 that the forward most clearance holes 13 also intersect the  
13 frusto-conical feature 18 and will act as vents for organic  
14 material during tang insertion after the square protrusion 23  
15 has engaged and filled square bore 19. The internal threads 16  
16 at the proximal end of the nail body 2 provide for instrument  
17 interface, as do slots 17. The threads 16 are used for  
18 attachment and the slots 17 for radial alignment. The internal  
19 threads 16 also engage the external threads 34 (FIG.8A) of end  
20 cap 6.

21 The tang assembly 3 has four equally sized and radially  
22 spaced tangs 21 which are preformed to radius R. The radius R  
23 (FIG.6B) on each tang 21 results in a dimension between the  
24 trailing ends of opposing legs which is greater than the outside  
25 diameter of tang body 20 and the bore diameter 14 of nail body  
26 2. The tang body 20 is circular in cross section and sized for  
27 a sliding fit within nail body bore 14 with a leading edge  
28 chamfer 22 which transitions into the leading protrusion 23  
29 which has a square cross section and leading end taper 24. Tang  
30 body 20 contains an internally threaded bore 25 which is the  
31 instrument interface for the instrument used to insert and  
32 deploy the tang. It must be noted that threaded bore 25 is not  
33 needed for tang retraction. FIG. 6A illustrates the deployed

1 shape of tang assembly 3 which is the shape it assumes after the  
2 tangs 21 have been forced through the tang exit portals 12 of  
3 nail  
4 body 2.

5 Insertion/deployment of the tang may occur after insertion  
6 of the nail body into the intramedullary canal. For tang  
7 assembly 3 insertion/deployment/retraction, the  
8 insertion/deployment/retraction instrument 47 (FIG. 3C) is  
9 employed. It has a shaft 44, one or more externally threaded  
10 end(s) 45 and guide 46. Shaft 44 is preferably circular in  
11 cross section with a diameter sized to allow reasonable  
12 flexibility or bending about the longitudinal axis as it travels  
13 through the nail body proximal bore 15 and distal bore 14 in  
14 order to follow the centerlines of both bores 14 and 15. The  
15 guide 46 provides a sliding fit in bore 14 and interacts with  
16 bore 14 in such a way as to center the shaft 44 within bore 14.  
17 Guide 46 also stabilizes shaft 44 in bore 14 to prevent shaft  
18 44 from buckling under axial compressive load encountered during  
19 tang assembly retraction. The insertion/deployment instrument  
20 is threaded into tang-threaded bore 25. The tang is now  
21 inserted through nail body bore 15 and into nail body bore 14.  
22 Since the distance between opposing tang legs 21 is greater than  
23 the bore diameter 14 due to radius R, the interference with bore  
24 14 forces the legs 21 inward in an elastic manner and insertion  
25 continues. As the tang assembly travels down bore 14, any  
26 organic material which has accumulated in bore 14 is pushed  
27 ahead and forced out through square bore 19 of nail body 2 and  
28 through clearance holes 13. Further insertion causes the tang  
29 assembly 3 leading square taper 24 to contact the square bore  
30 19 of the nail body 2. Since both cross sections are square,  
31 no engagement will occur until they are radially aligned which  
32 may or may not occur without some slight rotation of the tang  
33 assembly 3 using the insertion/deployment instrument. After

1 alignment occurs and by virtue of this alignment, the tang  
2 leading protrusion 23 will slide freely in square bore 19 and  
3 the tangs 21 and the nail body 2 tang portals 12 will now be  
4 aligned. The tang 3 continues past tang exit holes 12 and is  
5 fully inserted when the tang body leading edge chamfer 22 makes  
6 contact with the nail body frustro-conical feature 18 at point  
7 C of FIG. 3B. In this position, the tang leading protrusion 23  
8 protrudes through the end of nail body 2 to point A and the  
9 trailing end of the tangs 21 are just past tang portals 12. The  
10 tangs are now in position to be deployed. To deploy the tangs,  
11 an axial force is exerted by the insertion/deployment/retraction  
12 instrument 47 in the opposite direction as for insertion. This  
13 causes the tang assembly 3 to translate back up bore 14 and the  
14 sharp ends of tangs 21 to encounter tang portals 12. Since the  
15 tangs 21 were elastically compressed inward by bore 14 they will  
16 now spring outward forcing the sharp end of tang legs 21 into  
17 tang exit holes 12. Further translation of the tang assembly  
18 3 forces the tang legs through the tang exit holes 12. Due to  
19 the diameter and angle of the tang portals 12, the tangs 21 are  
20 formed in such a manner as to emerge almost perpendicular to the  
21 femoral cortex. Continued translation of the tang assembly 3  
22 causes the tangs 21 to penetrate the femoral cortex. During  
23 this time, tang leading square protrusion 23 is still engaged  
24 by the nail body square bore 19 thus preventing rotation of tang  
25 assembly 3 in bore 14 during deployment and preventing unwanted  
26 twisting of the tangs 21. The tang assembly 3 can be deployed  
27 fully or partially and is self locking in any position due to  
28 the almost perpendicular entry angle into the cortex. After  
29 deployment, the insertion /deployment/retraction instrument is  
30 unthreaded from tang threaded bore 25 and removed. The nail  
31 body 2 is now fixed axially and rotationally in the  
32 intramedullary canal. FIG.3A shows the tang assembly 3 in the  
33 fully deployed position having translated a distance from point

1 A in FIG. 3B to point B of FIG. 3A. The tangs 21 are fully  
2 retractable. They are retracted by applying a force on the tang  
3 assembly 3 with the insertion/deployment/retraction instrument  
4 42 in the opposite direction as deployment (opposite of arrow  
5 direction in FIG. 3A) until the tang assembly 3 comes to rest  
6 at points C and A in FIG. 3B.

7 Distal fixation of the nail body 2 can be accomplished  
8 without use of tang assembly 3. This is accomplished by using  
9 the cortical screws 7 (FIG. 1 and FIG. 2). The cortical screws  
10 7 are placed through the lateral femoral cortex and through  
11 clearance holes 13 in the nail body 2, then through the medial  
12 femoral cortex as shown in FIG. 2. The cortical screws are not  
13 used in conjunction with distal tang fixation and cannot be  
14 passed through clearance holes 13 if there is a tang assembly  
15 3 inserted into nail body 2.

16 Sleeve 4 is utilized to secure lag screw assembly 1 into  
17 clearance bore 11 after implantation of the lag assembly 1 and  
18 nail body 2 in the femur. The outside diameter L (FIG. 7B) is  
19 sized for a sliding fit in bore 11. The sleeve 4 has a circular  
20 bore 27 and a small length (D) of "double D" bore 31 at the  
21 leading end. The leading bore also contains a countersink 30.  
22 Between the leading and trailing ends is a tapered cross section  
23 29. The trailing outside diameter has a diamond knurl 26 and  
24 the circular bore 27 contains a countersink 28 at the trailing  
25 end. After the lag screw 1 is in position its trailing end  
26 protrudes partially or fully through nail body 2 bore 11. The  
27 leading end of sleeve 4 containing bore 31 is inserted into bore  
28 11 and the bore 31 aligned with the similarly shaped lag screw  
29 shaft 10. The sleeve 4 is inserted further into bore 11 thus  
30 mating, with the aid of countersink 30, the sleeve 4 and lag  
31 screw shaft 10. The sleeve 4 is placed within bore 11 such that  
32 the leading end of taper 29 or shoulder F in FIG. 7A is located  
33 properly with respect to bore 15 of nail body 2 ( FIG. 2 and 3).



1 The end cap 6 is inserted into the proximal end of nail body 2  
2 until external threads 34 (FIG.8A) contact the internal threads  
3 16 of nail body 2. The end cap 6 is then rotated clockwise by  
4 means of hexagonal recess 32 to engage the threads. End cap 6  
5 contains a patch of ultra high molecular weight polyethylene 35  
6 which acts as a thread locking element to help prevent unwanted  
7 loosening of end cap 6. As the end cap advances its leading end  
8 spherical radius 37 contacts sleeve taper 29 forcing sleeve 4  
9 against the opposite side of bore 11 indicated P (FIG. 4C). At  
10 this time the taper 29 is in contact with one end of bore 11 and  
11 the knurl surface 26 is in contact with the opposite end of bore  
12 11, indicated S in FIG. 4C. The taper 29 interaction with end  
13 cap spherical radius 37 prevents any translation of sleeve 4 in  
14 bore 11 in the direction of the lag screw and interaction of the  
15 end cap spherical radius 37 with the sleeve taper shoulder F  
16 prevents translation of the sleeve in the opposite direction.  
17 Interaction of knurled surface 26 of sleeve 4 and bore 11 in  
18 conjunction with interaction of end cap spherical radius 37 and  
19 sleeve 4 taper 29 prevents rotation of sleeve 4 in bore 11.  
20 Sleeve 4 is now fixed in translation and rotation. Therefore,  
21 lag screw 1 is now fixed in rotation but free in axial  
22 translation.

23 With the lag screw 1 fixed to one side of the fracture and  
24 the nail body 2 and sleeve 4 affixed to the other, the  
25 compression screw 5 can be utilized to draw the two assemblies  
26 together and compress the fracture. The externally threaded end  
27 40 of the compression screw 5 is inserted through the trailing  
28 end of sleeve 4 and mated with the internal threads 48 in the  
29 trailing end of lag screw 1. Advancing the screw utilizing  
30 drive recess 42 the threads engage. An ultra high molecular  
31 weight polyethylene patch 39 in the compression screw thread 40  
32 provides thread locking. As the threads further engage,  
33 compression screw chamfer 38 contacts sleeve 4 countersink 28

1 causing lag screw 1 to be drawn towards nail body 2 as the  
2 compression screw 6 is further rotated thus compressing the  
3 fracture.

4 It is to be understood that while we have illustrated and  
5 described certain forms of the invention, it is not to be  
6 limited to the specific forms or arrangement of parts herein  
7 described and shown. It will be apparent to those skilled in  
8 the art that various changes may be made without departing from  
9 the scope of the invention and the invention is not to be  
10 considered limited to what is shown in the drawings and  
11 described in the specification.

12

CLAIMS

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What is claimed is:

1. An intramedullary system having a lag screw assembly in combination with an intramedullary nail, for implantation in the intramedullary canal of a long bone, said intramedullary nail comprising an elongated body with a proximal end and a distal end, said proximal end having at least one radial bore, said lag screw assembly extending through said radial bore an adjustable distance, said lag screw assembly and said intramedullary nail including cooperating structure for adjusting and fixing said distance, wherein said distal end has a plurality of radial bores disposed therein, an anchoring device is adapted to be disposed in at least one of said plurality of radial bores and wherein said elongated body is cannulated with an axial bore at said proximal end and an axial bore at said distal end, said anchoring device disposed in said axial bore at said distal end, said anchoring device including at least one tang adapted to extend through at least one of said plurality of radial holes.

2. An intramedullary system of claim 1 wherein a plurality of radial bores are disposed in said distal end.

3. An intramedullary system of claim 2 wherein an anchoring device is adapted to be disposed in at least one of said plurality of radial bores.

4. An intramedullary system of claim 3 wherein said anchoring device is a cortical screw adapted to penetrate said long bone and extend through said at least one radial bore.

- 1     5. An intramedullary system of claim 3 wherein said elongated  
2     body is cannulated with an axial bore at said proximal end and  
3     an axial bore at said distal end, said anchoring device disposed  
4     in said axial bore at said distal end, said anchoring device  
5     including at least one tang adapted to extend through at least  
6     one of said plurality of said radial bores.  
7
- 8     6. An intramedullary system of claim 5 wherein said leading end  
9     of said lag screw assembly includes external bone screw threads  
10    for fixed engagement in said bone.  
11
- 12    7. An intramedullary system of claim 5 wherein said leading  
13    end of said lag screw assembly includes an internal tang and an  
14    aperture, said tang adapted to extend through said aperture for  
15    fixed engagement in said bone.  
16
- 17    8. An intramedullary system of claim 7 wherein said leading end  
18    of said lag screw assembly includes external bone screw threads  
19    for fixed engagement in said bone.  
20
- 21    9. An intramedullary system of claim 5 wherein said structure  
22    for securing said trailing end of said lag screw to said  
23    intramedullary nail comprises screw threads on said trailing  
24    end of said lag screw and a compression screw adapted for  
25    cooperating therewith.  
26
- 27    10. An intramedullary system of claim 5 wherein an axial bore  
28    extends from said radial bore through said proximal end, an end  
29    cap securely fastened in said axial bore frictionally contacting  
30    said structure for securing said trailing end of said lag screw  
31    assembly.  
32  
33

- 1 11. An intramedullary system of claim 10 wherein said structure  
2 for securing said trailing end includes a sleeve surrounding  
3 said trailing end and disposed in said radial bore, said  
4 trailing end slidable within said sleeve, said end cap  
5 frictionally contacting said sleeve and securing said sleeve in  
6 said radial bore.  
7
- 8 12. An intramedullary system of claim 11 wherein said structure  
9 for securing said trailing end includes screw threads on said  
10 trailing end and a compression screw inserted within said  
11 sleeve and cooperating with said screw threads to apply  
12 compression between said sleeve and said leading end of said lag  
13 screw assembly.  
14
- 15 13. An intramedullary system comprising a lag screw assembly  
16 in combination with an intramedullary nail, said lag screw  
17 assembly and said intramedullary nail sized and shaped for  
18 insertion into a long bone, said intramedullary nail having a  
19 proximal end with an axial bore, a distal end with an axial  
20 bore, said axial bores extending from said proximal end through  
21 said distal end, said proximal end having a radial bore, said  
22 lag screw assembly adapted to adjustably traverse said radial  
23 bore, said distal end having at least one radial bore, a tang  
24 assembly slidably disposed in said distal end of said axial  
25 bore, said tang assembly having at least one tang adapted to  
26 extend through said at least one radial bore in said distal end  
27 whereby sliding movement of said tang assembly extends said tang  
28 through said radial bore.  
29
- 30 14. An intramedullary system of claim 13 wherein said at least  
31 one tang is curved in the extended position.  
32  
33

- 1 15. An intramedullary system of claim 13 wherein said distal  
2 end has a plurality of radial bores and said tang assembly has  
3 a plurality of tangs adapted to extend through said plurality  
4 of radial bores.  
5
- 6 16. An intramedullary system of claim 13 wherein said axial  
7 bore of said proximal end of said intramedullary nail and said  
8 axial bore of said distal end intersect at an angle  
9 approximating anatomical shape.  
10
- 11 17. An intramedullary system of claim 16 wherein an  
12 insertion/deployment/retraction instrument is slidably disposed  
13 in said proximal axial bore and said distal axial bore, said  
14 instrument connected to said tang assembly whereby manipulation  
15 of said instrument slidably moves said tang assembly and deploys  
16 said tangs.  
17
- 18 18. An intramedullary system of claim 16 wherein said radial  
19 bore in said proximal end has an axis, said axis of said radial  
20 bore intersecting said axial bore of said proximal end at an  
21 angle to allow proper positioning of said lag screw assembly in  
22 said bone.  
23
- 24 19. An intramedullary system kit comprising a lag screw  
25 assembly, an intramedullary nail, a tang assembly with resilient  
26 tangs, cortical screws, a sleeve, a compression screw, an end  
27 cap and an insertion/deployment/retraction instrument, said lag  
28 screw assembly having a leading end and a trailing end, said  
29 leading end having attachment means for connecting said leading  
30 end to a portion of a bone, said intramedullary nail having a  
31 proximal end and a distal end, an axial bore through said  
32 proximal end and said distal end, a radial bore in said proximal  
33 end, and a plurality of radial bores in said distal end, said

1     tang assembly slidably disposed in said axial bore of said  
2     distal end, said instrument disposed in said intramedullary nail  
3     proximal axial bore and distal axial bore and connected to said  
4     tang assembly, said instrument adapted to slide said tang  
5     assembly to deploy said tangs through said radial bores in said  
6     distal end into said bone, said cortical screws adapted to be  
7     inserted through said radial bores in said distal end, said  
8     radial bore in said proximal end sized to permit passage of said  
9     leading end of said lag screw assembly, said lag screw assembly  
10    adapted to extend through said radial bore in said proximal end  
11    with said trailing end disposed in said axial bore, said sleeve  
12    sized to extend through said radial bore in said proximal end  
13    and slidably surround said trailing end of said lag screw  
14    assembly, said end cap adapted for connection with said axial  
15    bore in said proximal end of said nail and engage said sleeve  
16    for fixing said sleeve in said radial bore, said compression  
17    screw adapted to be connected with the trailing end of said lag  
18    screw assembly and said radial bore of said proximal end whereby  
19    manipulation of said compression screw will apply compression  
20    between said intramedullary nail and said lag screw assembly.

21

22

23     20. A method of fixing portions of a bone together comprising  
24     the steps of

25         providing an intramedullary system having a lag screw  
26     assembly for adjustable connection to an intramedullary nail by  
27     a compression screw, said intramedullary nail having a proximal  
28     end with an axial bore, a distal end with an axial bore, a  
29     radial bore in said proximal end, and a plurality of radial  
30     bores in said distal end, said lag screw assembly sized to  
31     traverse said radial bore in said proximal end, a cap screw in  
32     said axial bore of said proximal end, said cap screw for  
33     frictionally engaging and securing said lag screw assembly in

1     said radial bore, an anchoring device sl disposed in said axial  
2     bore of said distal end,  
3         inserting said intramedullary nail in said intramedullary  
4     canal of a portion of the bone,  
5         traversing said anchoring device through said radial bores  
6     in said distal end into said portion of said bone,  
7         traversing said lag screw assembly through said radial bore  
8     in said proximal end,  
9         deploying said lag screw in another portion of the bone,  
10         inserting said cap screw in said axial bore of said  
11     proximal end, and  
12         adjustably connecting said lag screw assembly and said  
13     intramedullary nail with said compression screw to gain  
14     compression between said lag screw assembly and said  
15     intramedullary nail.

16  
17     21. A method of fixing portions of a bone together comprising  
18     the steps of

19         providing an intramedullary system having a lag screw  
20     assembly for adjustable connection to an intramedullary nail by  
21     a compression screw, said intramedullary nail having a proximal  
22     end with an axial bore, a distal end with an axial bore, a  
23     radial bore in said proximal end, and a plurality of radial  
24     bores in said distal end, said lag screw assembly sized to  
25     traverse said radial bore in said proximal end, a cap screw in  
26     said axial bore of said proximal end, said cap screw for  
27     frictionally engaging and securing said lag screw assembly in  
28     said radial bore, an anchoring device disposed in said axial  
29     bore of said distal end, wherein said anchoring device further  
30     comprises a tang assembly slidably disposed in said axial bore  
31     of said distal end, said tang assembly having resilient tangs  
32     for traversing said radial bores in said distal end and engaging  
33     said portion of bone and an instrument for sliding said tang



1 assembly,  
2 inserting said intramedullary nail in said  
3 intramedullary canal of a portion of the bone,  
4 traversing said anchoring device through said radial bore  
5 in said proximal end,  
6 traversing said lag screw assembly through said radial bore  
7 in said proximal end,  
8 deploying said lag screw in another portion of the bone,  
9 inserting said instrument through said proximal end  
10 axial bore and said distal end axial bore to connect with said  
11 tang assembly,  
12 manipulating said instrument to slide said tang assembly  
13 to cause said tangs to traverse said radial bores and engage  
14 said portion of said bone,  
15 removing said instrument,  
16 inserting said cap screw in said axial bore of said  
17 proximal end, and  
18 adjustably connecting said lag screw assembly and said  
19 intramedullary nail with said compression screw to gain  
20 compression between said lag screw assembly and said  
21 intramedullary nail.  
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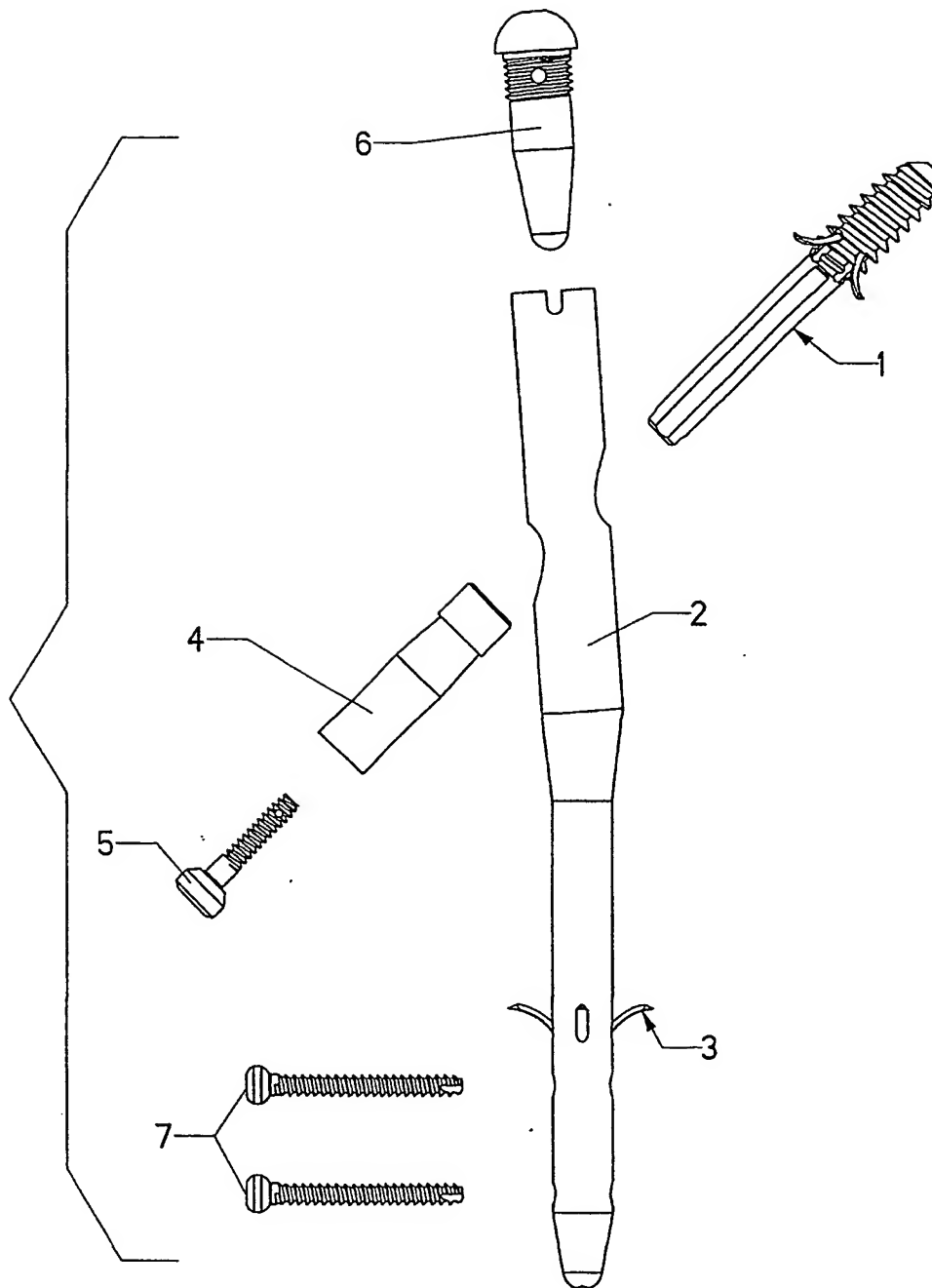


FIG. 1

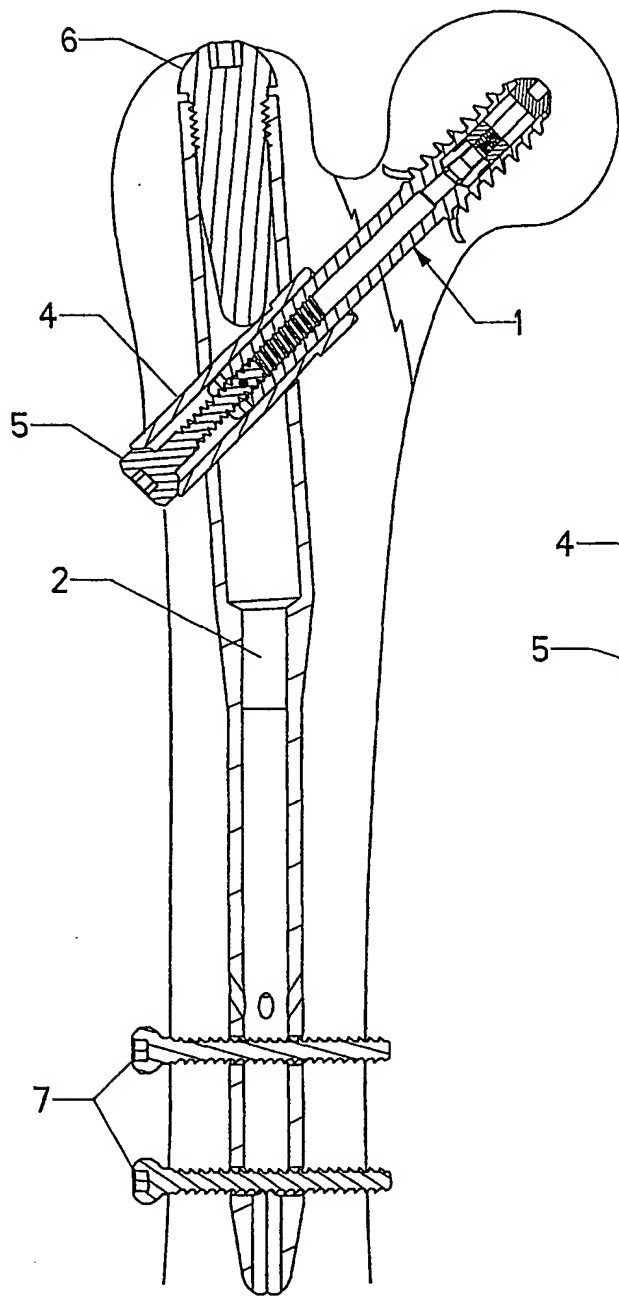


FIG. 2

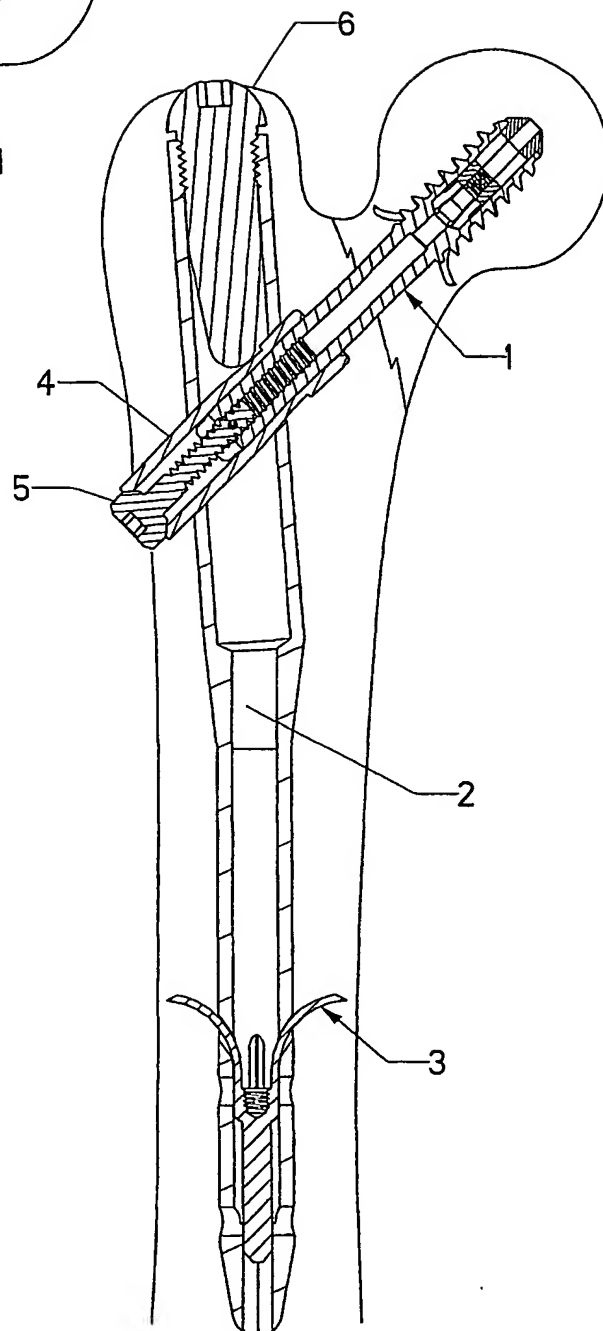


FIG. 3

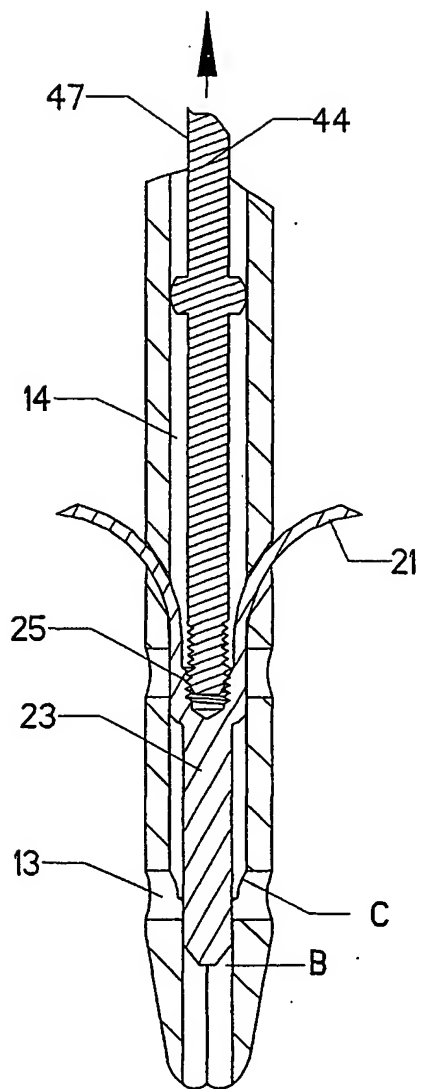


FIG. 3A

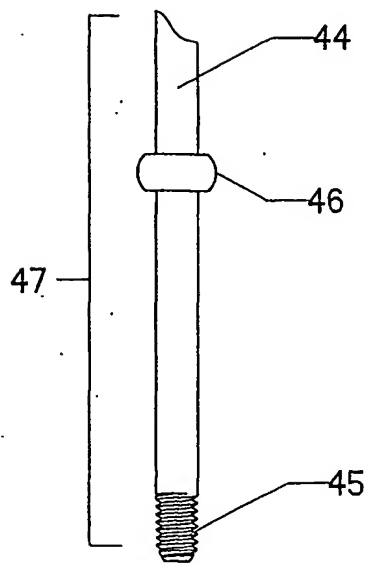


FIG. 3C

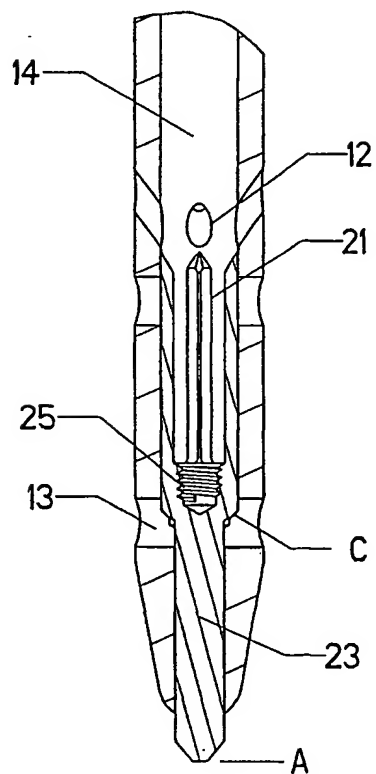


FIG. 3B

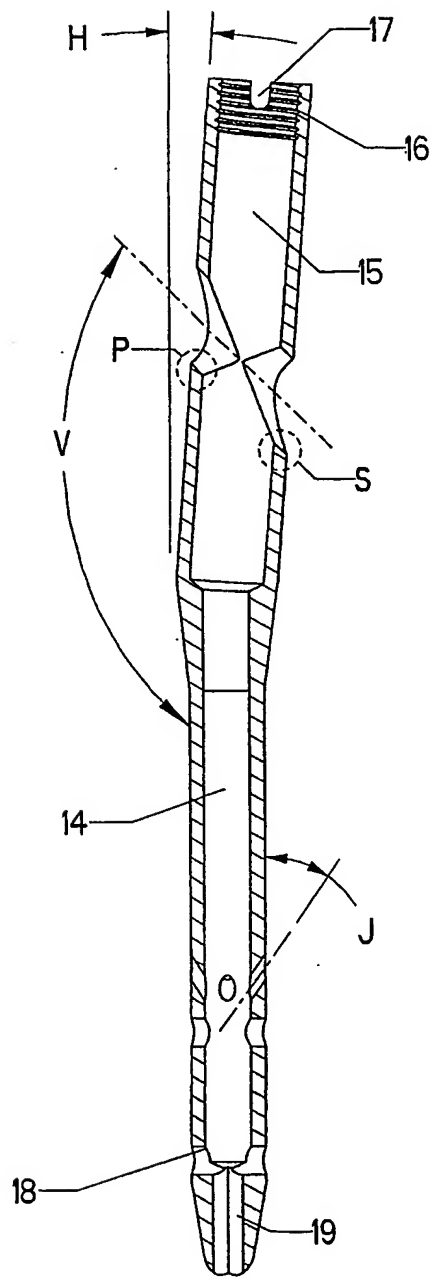


FIG. 4A

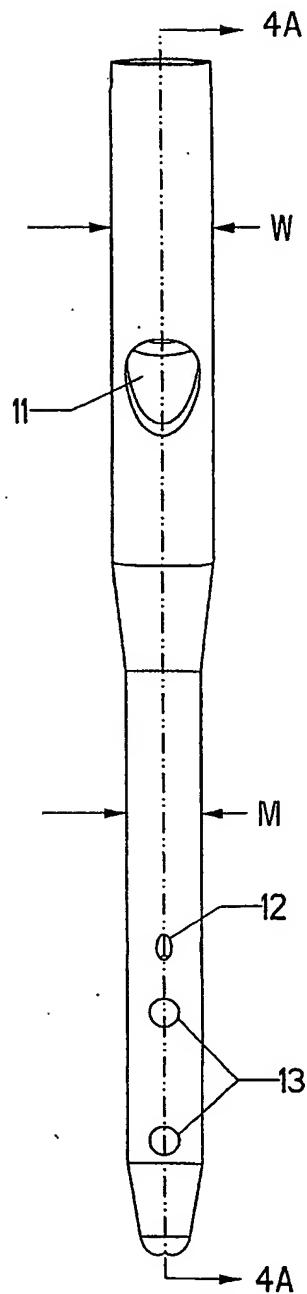


FIG. 4B

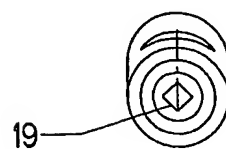


FIG. 4C

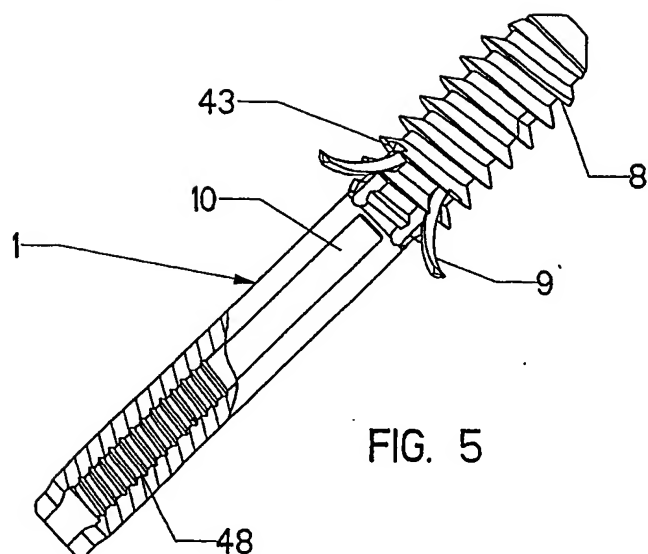


FIG. 5

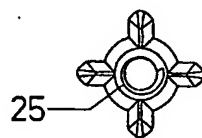


FIG. 6C

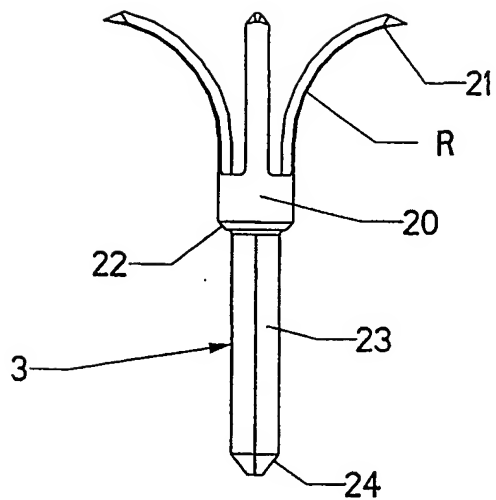


FIG. 6A

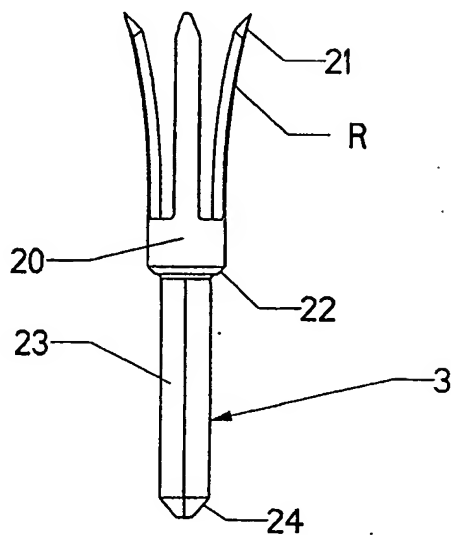


FIG. 6B

